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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,737	02/16/2006	Lukas Bestmann	5788	1195

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SHOEMAKER AND MATTARE, LTD
10 POST OFFICE ROAD - SUITE 110
SILVER SPRING, MD 20910

EXAMINER	
BERTAGNA, ANGELA MARIE	
ART UNIT	**PAPER NUMBER**
1637	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,737	BESTMANN, LUKAS	
	Examiner	Art Unit	
	ANGELA BERTAGNA	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37,39,42-51,53-56,66-68 and 70-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37,39,42-51,53-56,66-68 and 70-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. Applicant's response filed on January 18, 2008 is acknowledged. Claims 37, 39, 42-51, 53-56, 66-68, and 70-72 are currently pending. In the response, claims 37, 39, 42-51, 53-56, 66, 68, 70, and 71 were amended, and claims 1-36, 38, 40, 41, 52, 57-65, 69, 73, and 74 were cancelled.

Applicant's amendments to the claims have overcome the following objections and rejections: (1) the objection to claims 37-56 and 66-72, (2) the rejection of claims 37-56 and 66-72 under 35 U.S.C. 112, second paragraph, and (3) the rejection of claims 37-44, 46, 51, 54, and 56 under 35 U.S.C. 102(b) as being anticipated by Lipshutz. These rejections have been withdrawn.

Applicant's arguments regarding the rejections previously made under 35 U.S.C. 103(a) as they relate to the amended claims have been fully considered, but they were not found persuasive for the reasons discussed in section 8.

The following are new grounds of rejection necessitated by Applicant's amendments to the claims. Accordingly, this Office Action is made FINAL.

Specification

2. (A) Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means"

and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it recites legal phraseology, specifically, the word "said" in line 3. Correction is required. See MPEP § 608.01(b).

(B) The disclosure is objected to because of the following informalities: the "Brief Description of the Drawings" heading is missing.

Appropriate correction is required.

Claim Rejections – 35 USC § 112, 2nd paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 44, 45, 51, and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 44 and 45 are indefinite, because they recite the limitations of a cancelled claim - claim 1. As a result, the metes and bounds of these claims cannot be determined, and therefore, claims 44 and 45 are indefinite.

Claims 44 and 45 are further indefinite, because they recite the limitation "the support to which the composition of claim 1 is bound" in lines 2-3. There is insufficient antecedent basis

for this limitation in the claim, because claim 37 has been amended to recite that the composition is bound to a membrane rather than the support.

Claims 51 and 53 are indefinite, because they depend from claim 44.

Claim Rejections – 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 37, 39, 42-47, 51, 53-56, 66-68, and 70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pourahmadi et al. (WO 99/33559 A1) in view of Oultram et al. (WO 01/92569 A2).

Pourahmadi teaches methods and devices for purification and amplification of nucleic acids (see abstract, Figure 2, and page 10, line 17 – page 12, line 14).

Regarding claim 37, Pourahmadi teaches a cartridge for preparing reaction mixtures for chemical reactions with a sample that comprises an inlet (see Figure 2, reference number **103** and page 10, lines 17-23), an outlet (page 22, lines 7-10), and at least one support (see page 23, line 4 – page 24, line 21). The cartridge of Pourahmadi permits the sample to flow in the vertical direction (see Figure 2 and page 10 line 17 – page 12, line 11, where the sample flows vertically from sample port **103** to lysis chamber **119** and ultimately into waste chamber **139** or PCR reagent chamber **141** and PCR reaction chamber 143). Pourahmadi further teaches that the cartridge contains a lyophilized composition comprising dried PCR reagents that are

reconstituted by the sample (page 20, lines 1-5 and page 24, lines 23-35). Pourahmadi also teaches that the dried reagents may include DNA polymerase, reverse transcriptase, DNA primers and probes, buffer salts, and detergents (page 23, lines 29-37) and that the dried reagents may be "contained within a membrane material that can be employed as an interactive region by physical incorporation of the material into a region in communication with fluid channels (page 24, lines 5-8)." See also page 23, line 4 – page 25, line 10 for additional description.

Regarding claim 39, Pourahmadi teaches that the chemical reaction is PCR (page 10, lines 18-20).

Regarding claim 42, Pourahmadi teaches that the cartridge of claim 37 further comprises a device for applying elevated or reduced pressure (page 16, lines 17-32 and page 43, lines 1-10).

Regarding claim 43, Pourahmadi teaches that a capillary is attached above the inlet (see page 21, lines 19-28, where the needle and syringe are capillaries attached above the inlet).

Regarding claim 44, Pourahmadi teaches that one or more additional membranes are present between the inlet and support to which the composition is bound (page 24, lines 5-21; see also page 33, lines 10-27, and page 61, lines 4-25).

Regarding claim 45, Pourahmadi teaches membranes between the inlet and solid support to which the amplification composition is attached (page 10, lines 25-30 teaches a first membrane filter for capturing cells, page 24, lines 5-20 teaches a second membrane containing dried lysis reagents, page 33, lines 10-27 teach removal of particulate matter using a third membrane filter, and page 11, lines 12-18 teaches a fourth membrane filter for capturing nucleic acids).

Regarding claims 46 and 47, Pourahmadi teaches that at least one additional solid support, specifically a membrane, is designed so that polynucleotides can be bound thereto (see page 24, lines 5-21, page 33, lines 10-37, and page 61, lines 4-25).

Regarding claim 51, Pourahmadi teaches that a substance that absorbs solids is provided in the space between two membranes (page 27, lines 30-36; see also page 33, lines 10-22).

Regarding claim 53, Pourahmadi teaches that a membrane closest to the inlet is impregnated with a lysing agent (page 24, lines 5-16).

Regarding claims 54-56, Pourahmadi teaches that a unit for supplying a liquid, specifically an eluent, is provided above the support provided for binding polynucleotides (page 11, line 28 – page 12, line 2 and Figure 2). Pourahmadi also teaches using reduced pressure to make permeable a membrane separating a storage chamber from a reaction chamber (page 16, lines 17-32 and page 43, lines 1-10).

Regarding claim 66, Pourahmadi teaches a device for preparing reaction mixtures for chemical reactions, comprising:

(a) at least one cartridge according to claim 37 (see Figure 2 and page 10, line 17 – page 12, line 9 and above)

(b) at least one reaction device which is connected via an aperture to an outlet of the cartridge, and after charging with a reaction mixture, can be separated from the sample preparation device (page 12, lines 14-26).

Regarding claim 67 and 72, Pourahmadi teaches that the chemical reaction is PCR (page 12, lines 9-11).

Regarding claim 68, Pourahmadi teaches that the device comprises multiple cartridges (page 13, lines 4-10 and Figure 3).

Regarding claims 70 and 71, Pourahmadi teaches that the at least one reaction device can, after charging with a reaction mixture, be taken out of the sample preparation device and transferred into a device for carrying out and evaluating chemical reactions (see page 12, lines 13-26 and page 13, lines 4-13).

Pourahmadi does not teach that the PCR reagent composition coated on the membrane comprises the specific components recited in claim 37. Also, Pourahmadi teaches that the device comprises multiple cartridges (see Figure 3 and page 13, lines 4-10), but does not specifically teach that the device comprises three cartridges as required by claim 68.

Oultram teaches a dried composition for conducting PCR (see abstract and pages 2-3).

Regarding claim 37, the composition taught by Oultram comprises the following elements (see page 4, penultimate paragraph – page 5):

(i) a solution comprising a polymerase

(ii) $MgCl_2$ and KCl

(iii) dNTPs

(iv) two primers

(v) a stabilizer (e.g. trehalose)

(vi) a fluorescent reporter for detection of amplified products

(vii) further additives (Tris-HCl)

Oultram further teaches that the above composition is a lyophilizate (see page 4, penultimate paragraph – page 5, 2nd paragraph).

Oultram teaches that the above composition advantageously only requires a single addition of an aqueous target sample to the lyophilizate to produce an aqueous reaction mixture containing all of the components for PCR (page 3, paragraph 2). Oultram further teaches that inclusion of a fluorescent reporter in the composition permits homogenous detection of amplification products, thereby simplifying the detection process and minimizing contamination opportunities (page 3, paragraph 3). Finally, Oultram teaches that use of the above composition has the advantages of more defined reaction conditions, convenience, and long shelf life (page 3, paragraph 3).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to utilize the lyophilized composition taught by Oultram in the apparatus taught by Pourahmadi. As discussed above, Pourahmadi taught that the cartridge contained a composition comprising dried PCR reagents (*e.g.* DNA polymerase, reverse transcriptase, DNA primers and probes, buffer salts, and detergents) that are reconstituted by the sample (page 20, lines 1-5 and page 24, lines 23-35 and page 23, lines 29-37). Pourahmadi further taught that the dried reagents may be "contained within a membrane material that can be employed as an interactive region by physical incorporation of the material into a region in communication with fluid channels (page 24, lines 5-8)." Based on these teachings of Pourahmadi, an ordinary artisan would have been motivated to apply any known PCR composition, such as the lyophilized composition taught by Oultram, to a membrane for use in the apparatus of Pourahmadi with a reasonable expectation of success. An ordinary artisan would have been particularly motivated to use the composition taught by Oultram in the apparatus of Pourahmadi, because Oultram taught that the lyophilized composition permitted homogeneous product detection, thereby simplifying the detection